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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,014	07/31/2003	Christopher J. Calhoun	MA9606P	9368

7590 04/02/2007

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,014	CALHOUN ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 and 34-36 are pending in this application which claims benefit of U.S Provisional Application 60/409,137 filed on 09/09/2002 and claims benefit of 60/399,813 filed on 07/31/2002. Claims 30-33 and 37-50 have been cancelled.

Applicant's response filed on 12/28/2006 to Office Action mailed on 11/14/2006 has been acknowledged.

Claim Objections

Objection to claims 34-36 as being in improper dependent form is withdrawn in view of the amendment to claims provided with the aforementioned response.

Claim Rejections - 35 USC § 112

1. Rejection of claims 1-29 and 34-36 for reciting the term "substantially" is withdrawn. Applicant's arguments have been found to be persuasive.

2. Rejection of claims 34-36 for reciting dependency on a method claim is withdrawn in view of the amendment provided with the aforementioned response.

Claim Rejections - 35 USC § 102

1. Claims 1, 2, 4, 5, 14-17, 21, 22, and amended claims 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Arm et al. (WO 93/20859, Published 10/28/1993).

Arm et al. teaches, "biodegradable films comprising a polylactic/polygylcolic acid copolymer, a therapeutically effective amount of polypeptide growth factor, and a carrier

are provided." (See abstract). "Compositions are in the form of biodegradable polyester films, such as polylactic acid, polyglycolic acid ..." (See page 5, Lines 12-13). "Because polymers of enantiomeric lactides are crystalline and therefore more resistant to degradation than their racemic counterparts, it is preferred to used mixed enantiomer (e.g. poly (D, L-lactide acid)) polymers within the present invention." (See page 6, Lines 19-23). "Film thickness of less than about 50 μm are preferred, particularly film thickness between 5 and 20 μm." (See page 6, Lines 33-35). "The films may be affixed to the outer surface of an implantable or prosthetic device such as a screw, pin, plate, rod or artificial joint component." (See abstract). Arm et al. teaches the use of the film with non-biological implants such as a medical device, i.e. "rods" for "enhancing bone repair of bone fractures" (see abstract) and also with biological implants such as an allograft material, i.e. "demineralized bone matrix plugs" to induce new bone formation. "The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates, and the like. The films can also be used to coat bone filling materials, such as hydroxyapetite blocks, demineralized bone matrix plugs, collagen matrices and the like ..." (See page 13, Lines 9-19). In regards to resorbablity of the film Arm et al. teaches, "the unloaded *in vitro* degradation study showed mass loss from 50:50 and 85:15 PLA/PGA copolymer rods in the range of 80-95% by the 76-day point ..." (See page 15, Lines 25-27). In regards to the film characteristic being nonporous although Arm et al. is silent to this because the film has the same characteristic composition therefore products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the

prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Therefore, it is the examiners position that the film taught by Arm et al. would be nonporous for the reasons above.

Applicant's arguments have been considered but are not found to be persuasive. Applicant argues that Arm et al. is not prior art under 102(b) in view of the prior art publication date. Arm et al. was published on October 28, **1993** the earliest priority date given to applicant is July 03, **2002**. The prior art date was published more than one year before the Applicants effective filing date of July 03, 2002. Therefore, the prior art is correctly applied under the 35 U.S.C. 102(b) in the Arm et al. rejection. Applicant further argues that Arm et al. does not anticipate in view of the "consisting essentially of" language such as in claim 1 of instantly claimed application. Section 2111.03 [R-3] of the MPEP states, "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." The MPEP further states, "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." Applicant's claims or specification does not make clear that a carrier and a peptide growth factor would materially affect the basic or novel characteristic of the instantly claimed invention. Assuming arguendo applicant does provide evidence that a carrier and a peptide growth factor does materially affect the basic or novel characteristic of the instantly claimed invention the examiner points out that Arm et al. teaches a film of

100% polylactic acid and the addition of a carrier and peptide growth factor are a preferred embodiment but not a limiting embodiment of Arm et al.'s invention. (See page 3, Lines 36-37 and page 4, Lines 1-8). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In the instant case, Arm et al. does in fact also disclose the production of 100% polylactic acid film in the description of figure 1 (see page 4) and example 5 (see page 19).

2. Rejection of claims 1, 4, 7, 13-23, 25 and 29 under 35 U.S.C. 102(e) as being anticipated by Lahtinen et al. (US 2003/0059463, Published 03/27/2003) is withdrawn. Applicant's argument that the polymer base of the instantly claimed application is "selected from a group essentially of a lactide polymer and a copolymer of two or more cyclic esters" is not anticipated by "medium comprising biosorbable polymer" which lists suitable polymers that can be used including poly-L(lactic acid) and poly(D,L-lactic acid) is found to be persuasive.

Claim Rejections - 35 USC § 103

1. Claims 1, 4, 7-18, 21, 22 are rejected under 35 U.S.C. as being unpatentable over Hosseiny et al. (US 6451373, Published 09/17/2002). Applicant's arguments have been considered but are not found to be persuasive. Applicant argues that Hossainy et al. does not make obvious the claimed method of adhesion between an implant and surrounding tissue in view of the "consisting essentially of" language such as in claim 1 of instantly claimed application. Section 2111.03 [R-3] of the MPEP states, "The

transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." The MPEP further states, "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." Applicant's claims or specification does not make clear that a carrier and a peptide growth factor would materially affect the basic or novel characteristic of the instantly claimed invention. Absent such evidence the rejection is maintained.

2. Claims 1-6, and 21-29 are rejected under 35 U.S.C. as being unpatentable over Ledergerber et al. (US 4955907, Published 09/11/1990) in view of Calhoun et al. (US 2002/0001609 A1, Published 01/03/2002). Applicant's arguments have been considered but are not found persuasive. Applicant argues that Calhoun et al. is commonly owned at the time of the invention and therefore excluded as prior art. Examiner acknowledges that assignment is indeed the same however for a prior art reference to be excluded under 35 U.S.C. 103(c) the prior art date would have to fall under 35 U.S.C. 102(e), (f), or (g). The Calhoun et al. prior art falls under 102(a) date, i.e. published less than one year prior to instantly claimed application's earliest priority date.

3. Claims 1, 4, 7, 13-23, 25, 29, and amended claims 34-36 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lahtinen (US 2003/0059463 A1, published 3/27/2003).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant (i.e. organ) and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding a biological implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lahtinen teaches, "the invention relates to a medical device suitable for implantation into a human or animal, such as an implantable prosthetic device, a method of improving a human or animal body's acceptance of a medical device comprising at least one synthetic surface as well as a method of producing a device according to the invention." (See column 1, paragraph 1). "Said device comprises a core and a nucleic acid present in a biologically compatible medium ..." (See column 6, paragraph 21). "The biologically compatible medium is a biostable polymer, a biosorbable polymer, a biomolecule, a hydrogel polymer or fibrin." (See column 7, paragraph 24). "Biosorbable polymers that may be used include, but are not limited to, poly-(L-lactic acid), ... poly(D,L-lactic acid) ...." (See column 26, paragraph 112). Lahtinen further teaches, "In one aspect there is a solid/solid solution of polymer and drug. This means that the drug and the polymer both are soluble in the same solvent and have intimately admixed in the presence of that solvent. The drug and polymer can be applied in various ways, such as by simply immersing the implant into the solution or by spraying the solution onto the implant. The polymer can be porous or nonporous on the implant" (See column 27, paragraph 112). Lahtinen teaches that the implant to be

"immersed or sprayed" with the solution can be an implant such as an "organ", allografting material such as a "vascular graft" to be implanted in soft tissue, or a prosthesis such as a "pacemaker lead" or "cardiac assist device" to be implanted in soft tissue. "A medical implant maybe an implantable prosthetic device, and more particularly, a cardiovascular implant or tissue implant, as well as blood-contacting medical implant, a tissue contacting medical implant, a bodily fluid-contacting medical implant, an implantable medical device, an extracorporeal medical device, an artificial heart, a cardiac assist device, an endoprosthesis medical device, a vascular graft, a stent graft, a heart valve, a cardiovascular patch, a temporary intravascular implant, an annuloplasty ring, a catheter, a pacemaker lead, a biosensor, a chamber for holding living cells, an organ implant, or a bioartificial organ." (See column 8, paragraph 35). "Preferred devices are implantable in the body, and include cardiovascular implants, tissue implants, artificial organs, such as pancreas, liver, and kidney, and organ implants, such as breast, penis, skin, nose, ear, and orthopedic implants" (See column 23, paragraph 129).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Lahtinen does not anticipate the instant invention since one cannot immediately envisage the utilization of polylactic acid polymers. Although, Lahtinen teaches a porous or nonporous coating, Latinen does not specifically teach a nonporous polylactic acid coating.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Although, Lahtinen does not anticipate the instant invention it would have been obvious to one of ordinary skill in the art at the time of the presently claimed invention to use polylactic acid for the film to coat the implant. One would have been motivated to use polylactic acid as the polymer base coating for vascular graft because Lahtinen makes ploylactic acid a preferred embodiment for coating a vascular graft. (See pargraph 135). Thus if one desired to make a vasculature coated graft, a skilled artisan would utilize a polylactic acid polymer base coating suggested by Latinen. One would also be motivated to form a nonporous polymer film because Lehtinen teaches that a nonporous film "serves to provide tear resistance" of the film. (See paragraph 130). For the foregoing reasons the instantly claimed method of attenuating adhesions between an implant and surrounding tissue is made obvious.

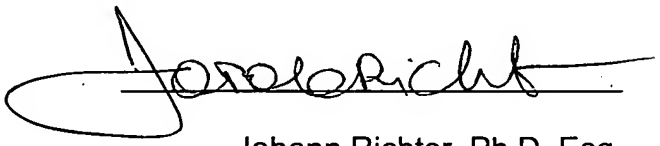
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616



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